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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,333	08/22/2003	James H. Brauker	DEXCOM.011A	8284

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EXAMINER

KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,333

Applicant(s)

BRAUKER ET AL. *Ch*

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) 3-6, 8, 11, 13, 14, 16, 18-30 and 64-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7, 9, 10, 12, 15, 17, 31-63 and 67-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of species A, F, I, L, N, a, and g in the reply filed on 8/30/2004 is acknowledged. It is noted that the Applicants assert a listing of generic claims that is different from the Examiner's listing of generic claims in the Office Action mailed on 8/13/2004. After careful consideration, the Examiner maintains the listing of generic claims as well as the breakdown of species as set forth in the Office Action of 8/13/2004 as proper in view of the fact that Applicant did not submit any arguments that run contrary to the Examiner's position.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 9-10, 12, 15, 36, 41, 44-60, 67, 68, 70, 72, and 74-76 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,833,603 to Kovacs et al. (Kovacs). In regard to claim 1, Kovacs discloses an implanted sensor that comprises a sensing region 128 for the transport of gases or ions. (Fig. 10 of Kovacs). In regard to claims 9-10, Kovacs disclosed an implanted sensor that comprises a continuum of sensing region 128 for the transport of gases or ions. (Fig. 10 of Kovacs). In regard to

claim 12, Kovacs teaches a sensing region 128 on the left side of the housing (where electrode 130 is located) and a curved second major surface on the right side of the housing (where reference numeral 36 is located). (Fig. 10 of Kovacs). In regard to claim 15, the sensing region 128 is located on the apex of the curved first surface of the housing by virtue that the sensing region completely encapsulates the curved first surface. (Fig. 10 of Kovacs). Kovacs also teaches a curved second surface located on the right side of the sensing region on the housing (where reference numeral 36 is located). (Fig. 10 of Kovacs). In regard to claim 41, the sensing portion 128 is located on a major surface where electrodes 130 and 132 are located. In regard to claim 46-51, the sensing region is located on the first major surface on the left side of the housing. (Fig. 10 of Kovacs). The sensing region 128 is spaced away from the edges of the first major surface by at least 50% of the width of the first major surface. In regard to claims 53-56, these claims of the present application appear to be trying to define the contour of the first major surface by referencing an imaginary reference plane. The reference plane, however, does not seem to be a physical claimed structure and can, therefore, move anywhere relative to the contoured surface within the boundaries set by the claim. The contours of the first major surface on the left side of the housing (where electrode 130 is located) of Kovacs meet these limitations because of its overall shape of the contoured surface. (Fig. 10 of Kovacs). In regard to claim 67, a porous bio-interface material 126 is disclosed. (Fig. 10 of Kovacs). In regard to claim 68, the bio-interface material is porous and the material is configured in such a way that the sensing region achieves equilibrium. (column 25, lines 25-35 of Kovacs). In regard to claims 70 and

72, Kovacs teaches a sensing region 128 on a convex major surface of the body where electrodes 130 and 132 are located. (Fig. 10 of Kovacs). In regard to claim 74, Kovacs teaches a sensing means 128 and a housing means in the form of the capsule.

4. Claims 1, 7, 67, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,049,727 to Crothall. In regards to claim 1 and 69, Crothall discloses an implanted sensor for measuring glucose that comprises a sensing region 104. (Fig. 8 of Crothall). In regard to claim 67, a wire mesh covers a portion of the sensing region 104. (column 17, lines 62-67 of Crothall).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. (Kovacs) as applied to claim 1, and further in view of U.S. Patent Application Publication 2003/0125613 to Enegren et al. (Enegren). Kovacs teaches an implantable sensor for measuring gases and/or ions. (column 15, lines 16-45 of Kovacs). Kovacs does not teach a particular location for the implanted sensor. Enegren teaches that a pH (a measurement of hydrogen ions) can be

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measured in subcutaneous tissue (paragraph 0014 of Enegren), which would fulfill the requirements of providing a location for the implantable sensor as needed by Kovacs. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to implant the sensor in subcutaneous tissue as disclosed by Enegren since a location for the implantable sensor is required and Enegren teaches one such location.

7. Claims 17 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. (Kovacs) as applied to claim 1, and further in view of U.S. Patent 6,454,710 to Ballerstadt et al. (Ballerstadt), and further in view of U.S. Patent 4,197,840 to Beck et al. (Beck). Kovacs teaches that the shape of the housing is cylindrical and, therefore, has a circular cross-section but Kovacs teaches that other shapes can be used. (column 8, lines 33-35 of Enegren). Ballerstadt teaches that a rectangular cross-section is a suitable substitute for circular one. (column 8, lines 23-27 of Ballerstadt). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the rectangular cross-section for the circular cross-section since Kovacs teaches other shapes can be used and Ballerstadt teaches one such shape. The combination does not teach that the rectangular shape has rounded corners but Beck teaches that rounding of edges is necessary for implanted bodies. (column 2, lines 51-56 of Beck). The rounding of edges prevents injuries to the internal tissues of the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made

to round the edges of the rectangular housing as disclosed by Beck since such rounding is necessary in implanted devices since such rounding prevents injuries to internal tissues.

8. Claims 61-63 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. (Kovacs) and further in view of U.S. Patent 4,927,407 to Dorman. Kovacs disclosed an implanted sensor that comprises a sensing region 128 for the transport of gases or ions. (Fig. 10 of Kovacs). Kovacs does not teach a particular material for the housing. Dorman teaches that biocompatible epoxy is a suitable material. (column 4, lines 14-16 of Dorman). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the biocompatible epoxy of Dorman since a material is required for the housing and Dorman teaches one such material.

9. Claims 31-32, 35 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. (Kovacs) and further in view of U.S. Patent 6,409,674 to Brockway et al. (Brockway). In regard to claims 31-32, Kovacs teaches an implantable body that includes a sensing region 128 located on the outside surface (the first surface) of the housing. (Fig. 10 of Kovacs). Kovacs does not teach that the outside surface comprises anchoring material for supporting tissue ingrowth. Brockway teaches a mesh on the outside surface of an implantable device so that an implanted device is secured at a particular location. (Figs. 3C and column 8,

lines 10-57 of Brockway). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the mesh of Brockway with the invention of Kovacs since the implanted sensors are secured at particular locations. Kovacs teaches a second surface in the form of the inside of the mesh. In regard to claim 35, Kovacs disclosed an implanted sensor that comprises a sensing region 128 for the transport of gases or ions. (Fig. 10 of Kovacs). Kovacs does not teach a mechanical anchoring mechanism formed on the body. Brockway teaches a variety of securing mechanism so that an implanted device is secured at a particular location. (Figs. 3A-3D and column 8, lines 10-57 of Brockway). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use one of the securing mechanisms of Brockway with the invention of Kovacs since such mechanisms secure implanted sensors at particular locations. In regard to claim 71, Kovacs teaches an implantable body that includes a sensing region 128 located on the outside surface of the housing (the first surface). (Fig. 10 of Kovacs). Kovacs does not teach that the outside surface comprises anchoring material for supporting tissue ingrowth. Brockway teaches a mesh on the outside surface of an implantable device so that an implanted device is secured at a particular location. (Figs. 3C and column 8, lines 10-57 of Brockway). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the mesh of Brockway with the invention of Kovacs since the implanted sensors are secured at particular locations.

10. Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. (Kovacs) and further in view of U.S. Patent Application Publication 2003/0114735 to Silver et al. (Silver). In regard to claim 32, Kovacs teaches an implantable body that includes a sensing region 128 located on the left surface of the housing. Kovacs also teaches a right surface of the housing. (Fig. 10 of Kovacs). Kovacs does not teach a particular material for the housing. Silver teaches that glass, ceramic, or metal are suitable materials. (paragraph 0203 of Silver). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the glass, ceramic, or metal as disclosed by Silver since a material is required for the housing and Dorman teaches one such material.

11. Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. (Kovacs) as applied to claim 1. Kovacs does not teach a particular radius of curvature but Kovacs does teach that the shape of the implant can be changed. This teaching provides a clear suggestion that the shape of the implant can be modified and that the determination of the most appropriate shape by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-

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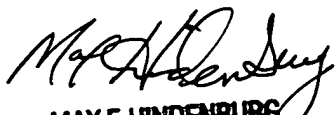
0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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